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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,793	08/04/2003	Glaucia Paranhos-Baccala	110048.01	5572

25944 7590 09/07/2007

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,793	PARANHOS-BACCALA ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-36,41-43 and 46* is/are pending in the application.

4a) Of the above claim(s) *8-15, 17-20, 22-36, and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7, 16, 21, and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 7-36, 41-43 and 46 are pending.
Claims 8-15, 17-20, 22-36, and 41-43 are withdrawn.
Claims 1-3, 7, 16, 21, and 46 are examined on the merits.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/17/2007 has been entered.

This Office Action is in reply to Applicants' correspondence of 5/17/2007. Claim(s) 4-6, 37-40, 44, 45, 47, and 48 is/are cancelled; claim(s) 8-15, 17-20, 22-36, and 41-43 is/are withdrawn; no claim(s) has/have been newly added; claim(s) 1 and 7 has/have been amended.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put this application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is **NON-FINAL**.

Withdrawn Claim Objection

1. The objection to claim 7 as presented in the previous Office Action is **WITHDRAWN** in light of the amendments to the claim.

New Claim Objections

2. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 2 and 3 depend from claim 1, where claim 1 recites the structural limitations of the claimed isolated nucleic acid. The dependent claims require only the additional limitations that the claimed nucleic acid can be isolated from at least one of a specified human chromosome: chromosomes 1, 3, 6, 7, or 16 in the case of claim 2, or chromosome 3 in the case of claim 3. However, claims 2 and 3 do not recite any additional structural limitations of the claimed nucleic acid molecules, nor does the specification provide for any structural limitations that would differentiate the nucleic acid molecule of claim 1 from the nucleic acid molecules of claims 2 and 3. As such, the molecule of claim 1 is not different from the molecule of dependent claim 2 or the molecule of dependent claim 3, and the dependent claims do not further limit the molecule of the independent claim 1.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Withdrawn Claim Rejections - 35 USC § 112 1st Enablement

3. The rejection of claims 5 and 6 under 35 USC 112 1st ¶ for lack of enablement is **WITHDRAWN** in light of the cancellation of those claims.

Withdrawn Claim Rejections - 35 USC § 102

4. The rejection of claims 1-3, 5, 6, and 16 under 35 USC 102 as anticipated by the teachings of Brennan (US Patent 5,474,796) is **WITHDRAWN** in light of the cancellation of claims 5 and 6, and the amendments to claim 1, from which claim 2, 3, and 16 depend.

5. The rejection of claim 7 and 21 under 35 USC 102 as anticipated by the teachings of Chanda et al is withdrawn in light of the amendments to claim 7, from which claim 21 depends.

New Claim Rejections - 35 USC § 102

In the rejection of the pending claims, the required sequence elements of the claimed nucleic acids are considered an inherent property of human nuclear DNA and RNA from the plasma of human multiple sclerosis patients. Thus the cited references anticipate the broadly claimed nucleic acid molecules even though the cited references may not specifically disclose the nucleic acid or amino acid sequences recited in the claims. Concerning the inherent nature of the claimed sequence in human genomic DNA and RNA from the plasma of human MS patients, MPEP 2112 clearly indicates that: something which is old does not become patentable upon the discovery of a new property; and that the inherent feature of a product need not be recognized in the prior art at the time of invention.

As such, in the rejection of claims under 35 USC 102 the USPTO has basis for believing that the claimed nucleic acid molecules are an inherent part of the nucleic acids referenced in the cited prior art. The MPEP in chapter 2100 states:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the rejection of claims, the specification does not exemplify or provide any indication that the sequence disclosed as SEQ ID NO: 2 and encoding the amino acid of SEQ ID NO: 31 is not an inherent part of the human genome. As such there is no evidence supporting any structural difference between the claimed nucleic acids and the nucleic acids of the cited prior art.

6. Claims 1-3, 7, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perron et al (1997).

Perron et al teaches a sample of RNA extracted from the plasma of a human MS patient (p.7584 – RNA extraction, cDNA synthesis, and PCR amplification from MS plasma samples). The RNA extracted from the plasma of a human MS patient inherently comprises a transcript that is a sequence encoding an expression product where the expression product comprises SEQ ID NO: 31.

Regarding claims 1-3 and 16, as detailed above, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that comprises SEQ ID NO: 31. Regarding claims 2 and 3, the required limitation that the isolated nucleic acid 'can be isolated from' any particular chromosome does not further limit the structural requirements of the claimed nucleic acid, and as such because prior art

anticipates the nucleic acid of claim 1, the nucleic acid of the prior art also anticipates the nucleic acids of claims 2 and 3. With regard to claim 16, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Regarding claims 7 and 21, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that comprises SEQ ID NO: 31, where the RNA is a transcription product. With regard to claim 21, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

7. Claims 1-3, 16, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Seifarth et al (1998).

Seifarth et al teaches an analysis of human genomic DNA digested with either BamHI or HindIII (Fig 3). Such DNA includes a nucleic acid molecule comprising SEQ ID NO: 2 considering that SEQ ID NO: 2 is an inherent part of the human genome, and that SEQ ID NO: 2 itself does not contain either a BamHI of HindIII restriction site (as such the sequence of SEQ ID NO: 2 would remain intact in the DNA of Seifarth et al.

Regarding claims 1-3, 16, and 46, as detailed above, the digested human DNA of Seifarth et al inherently comprises a nucleic acid molecule comprising SEQ ID NO: 2. Regarding claims 2 and 3, the required limitation that the isolated nucleic acid 'can be isolated from' any particular chromosome does not further limit the structural requirements of the claimed nucleic acid, and the digested DNA of Seifarth et al comprise DNA from every human chromosome. With regard to claim 16, in so far as

the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Response to Remarks

The rejection of claims as anticipated by the prior art as set forth in the previous Office Action have been withdrawn, making Applicants arguments in traversal of those rejections (p.8 of Remarks) moot. New grounds of rejection based on the inherent property of RNA from the plasma of a human MS patient (i.e. that it contains a transcription product that encodes SEQ ID NO: 31) and human DNA (that it contains SEQ ID NO: 2) are set forth in this Office Action. Thus while claim 46 (drawn to a nucleic acid molecule comprising SEQ ID NO: 2) was preciously indicated as free of the prior art, and the transcription product resulting from transcription of the entirety of SEQ ID NO: 2 was suggested as free of the prior art, upon further review of the teachings of the specification and the teachings of the prior art the new rejections under 35 USC 102 are set forth.

Conclusion

No claim is allowable. No claim is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

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Stephen Kapushoc
Art Unit 1634